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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) UTSJ:041US
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Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

applicant/inventor.



Signature

assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/06)

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attorney or agent acting under 37 CFR 1.34.

January 21, 2011

Date

Registration number if acting under 37 CFR 1.34 _____

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

*Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Dhiraj SARDAR *et al.*

Serial No.: 10/543,001

Filed: May 23, 2006

For: METHOD AND APPARATUS FOR
DIAGNOSING NEOVASCULARIZED
TISSUES

Confirmation No.: 1190
Group Art Unit: 3768
Examiner: BRUTUS, Joel F.
Atty. Dkt. No.: UTSJ:041US / 10507807

ARGUMENTS IN SUPPORT OF THE REQUEST FOR PRE-APPEAL BRIEF REVIEW**A. The Claims Are Novel Over Dreher**

The Examiner's rejection of claims 1-5, 9-13, 17-18, and 23-34 as being anticipated by Dreher (U.S. Patent 5,303,709) as evidenced by Van de Velde (U.S. Patent 5,568,208) should be withdrawn, because the rejection is legally and factually flawed.

I. Dreher Does Not Disclose All Elements of the Claims

It is well established that for a publication to anticipate a claim it must disclose all elements of the claim. *See, e.g., Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). The claims included in the rejection are directed to methods of diagnosing an ocular disease involving neovascularization or to methods of detecting neovascularized tissue. Dreher does not anticipate the current claims because Dreher does not provide any disclosure concerning the detection of neovascularized tissue or the diagnosis of an ocular disease involving neovascularization. Dreher does not even mention neovascularization or ocular diseases involving neovascularization. Thus, it is clear that Dreher cannot teach all of the elements of the claims included in this rejection.

The Examiner appears to recognize the deficiency in Dreher's disclosure, but attempts to gloss over it by generalizing neovascularized eyes as simply "diseased eyes," and then arguing that Dreher also discloses "diseased eyes" (Action, p. 3). This is legally impermissible.

While a pending claim is given its broadest reasonable interpretation, this interpretation must be consistent with the specification as it would be understood by a person of ordinary skill in the art. *See* MPEP § 2111. The Examiner's interpretation of the claims goes well beyond a broad interpretation to the point of completely reading "neovascularization" out of the claims. Moreover, the Examiner's interpretation is not consistent with the specification. The specification clearly states that "Ocular neovascularization is the formation of new blood vessels in the development of diseases such as, for example, macular degeneration and diabetic retinopathy." (Specification, para. [0006]). The specification further discloses that such neovascularization occurs in retinal and RPE/choroidal tissue (Specification, para. [0007], [0014]). While it is true that neovascularized eyes are diseased eyes, it is not true that all diseased eyes are neovascularized. This is evident from Dreher, in which thickening of the nerve fiber layer at the fundus of the eye results in diseased eyes of a different type, *e.g.*, glaucoma (Dreher, col. 3, ln. 61-64). As mentioned above, Dreher does not mention ocular diseases involving neovascularization.

It is, therefore, clear that Dreher does not provide an anticipating disclosure of all of the elements of any of the current claims. Accordingly, this rejection should be withdrawn.

2. The Examiner's Assertion That There Is No Difference Between Reflected Light and Backscattered Light Contradicts Fundamental Laws of Physics

The current claims refer to a light beam that is "backscattered." It is well-known in the art that backscattered light and reflected light are different. The *law of reflection* states that the angle at which the wave is incident on the surface equals the angle at which it is reflected. Scattered or diffuse reflections, on the other hand, result when the light is forced to deviate from

a straight trajectory by one or more non-uniformities in the medium through which they pass. Backscattered light is a type of scattered light for which the change in the angle of its trajectory is greater than 90°. Despite the fact that these are fundamental laws of physics, the Examiner disagrees that there is a difference between backscattered light and reflected light (Action, p. 8). While it is possible some of the backscattered light will be scattered such that it follows the trajectory of regular reflected light, the backscattered light can be distinguished from the reflected light because the polarization of the backscattered light will be different.

The Examiner's reliance on Dreher's FIG. 1 and FIG. 7 to rebut Applicants' arguments is also factually flawed. In particular, the apparatus depicted in FIG. 7 includes pinhole diaphragm 73. As Dreher explains, pinhole diaphragm 73 is included *to eliminate* light not returning from the selected focal plane (col. 7, ln. 29-34). Thus, Dreher is using the pinhole diaphragm to eliminate light coming from deeper within the tissue (*i.e.* light not from the selected focal plane). To anticipate, a reference must clearly and unequivocally disclose the claimed invention or direct those skilled in the art to the without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference. *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1083 (Fed. Cir. 2008). In the present rejection, however, the Examiner has impermissibly picked elements from various disclosures in Dreher (*e.g.*, FIGs. 1 and 7) without regard to the incompatibilities of these disclosures.

3. Conclusion

The Examiner failed to establish a *prima facie* case of anticipation for at least the reasons discussed above. Applicants, therefore, request the withdrawal of this rejection.

B. The Rejections Under 35 U.S.C. §103(a) Are Overcome

The Examiner raises three obviousness rejections: (1) claims 6-8 and 14-16 are rejected as allegedly being unpatentable over Dreher *et al.* (U.S. Patent 5,303,709) in view of Glaser *et al.*

(U.S. Patent 5,767,079) or Lerrick *et al.* (U.S. Patent 5,670,151); (2) claim 19 is rejected as allegedly being unpatentable over Dreher in view of Hay (U.S. 5,632,282); and (3) claims 20-21, 35, 37, 39, and 42 are rejected as allegedly being obvious over Dreher in view of Hay and further in view of the Trachtman patent (U.S. 5,002,384).

Dreher is the primary reference in each of these rejections. As discussed above, Dreher does not provide any teachings concerning the detection of neovascularized ocular tissue or the diagnosis of an ocular disease involving neovascularization. Rather, the Examiner has taken the legally impermissible approach of reading “neovascularization” out of the claims. Furthermore, although Glaser and Lerrick are cited as teaching methods of treating or controlling ophthalmic disorders associated with neovascularization, such teachings do nothing to cure the deficiencies in Dreher. There is still no teaching or suggestion concerning the detection of neovascularized tissue or the diagnosis of an ocular disease involving neovascularization.¹

Moreover, disclosures in Dreher teach away from the presently claimed invention and fail to provide a reasonable expectation of success in achieving the claimed invention. For example, and as discussed above, the apparatus depicted in Dreher’s FIG. 7 includes pinhole diaphragm 73 that is used to eliminate light not returning from the selected focal plane (col. 7, ln. 29-34), thus eliminating much of the backscattered light. Additionally, Dreher teaches “discarding any data, that is any light rays, that are returning from the eye having altered polarization.” (Dreher, col. 7, ln. 24-26). Dreher further states that “the confocal topographical mapping technique can be enhanced by discarding all light information in which the light rays have been altered in their polarization state.” (Dreher, col. 7, ln. 43-46). As mentioned above, backscattered light would have an altered polarization and would, therefore, be discarded according to Dreher’s teachings.

Although Dreher does mention detecting light with an altered polarization state in some circumstances (*see e.g.*, col. 7, ln. 50-53), there is no teaching that this information could be used to detect neovascularization nor is there any guidance of when or how to do so. Accordingly, a person of ordinary skill in the art would not have had a reasonable expectation of success in achieving the claimed invention. A reasonable expectation of success is required to establish a *prima facie* case of obviousness. MPEP § 2143.02.

In view of the above, the current claims are patentable over the cited references. Applicants, therefore, request the withdrawal of the obviousness rejections.

C. Conclusion

In view of the foregoing, it is respectfully submitted that each of the pending claims is in condition for allowance.

Respectfully submitted,



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¹ None of the other secondary references provide any teaching or suggestion concerning the detection of neovascularized tissue or the diagnosis of an ocular disease involving neovascularization. The Examiner cites Hay as teaching a chin rest. Trachtman describes using infrared light to monitor a patient's eye position.